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[Docket No. 00N-0086]
Amendment of Regulations regarding Certain Label Statements on Prescription Drugs

Merck & Co., Inc, is a leading worldwide human health product company. Merck's corporate strategy – to discover new medicines through breakthrough research – encourages us to spend more than $2 billion, annually, on worldwide Research and Development (R&D). Through a combination of the best science and state-of-the-art medicine, Merck's R&D pipeline has produced many of the important pharmaceutical products on the market today.

As a leading health care company, Merck is very interested in, and well qualified to comment on the FDA proposal to amend regulations regarding certain label statements on prescription drugs and biological products, i.e., to replace the statement "Caution: Federal law prohibits dispensing without prescription" with "Rx (or ℞) only" and to remove the requirement that certain habit-forming drugs bear the statement "Warning-May be habit-forming."

General Remarks:

Merck commends the FDA for this endeavor as part of its implementation of the Food and Drug Modernization Act of 1997. Merck believes that this revision to labeling will result in more space on the product's label, helping to decrease the possibility of medication errors by enhancing the readability of the label text. Based on the Guidance for Industry – Elimination of Certain Labeling Requirements (Procedural Guidance #3, revised July 1998) Merck has, in fact, implemented this revision in the packaging of all prescription products and biological products distributed by the Company.

Comment:

Merck is providing comments on one section in the description of the proposed regulation. This concerns the type of font specified for printing. In both Federal Register notices concerning the Rule (Vol. 65, No. 69, April 10, 2000, page 18935 and Vol. 65, No. 78, April 21, 2000, page 21378) the following statement is made in a footnote "The ℞ symbol appears in bold in this

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document because of type-setting limitations, however, it should not be bolded when used on the product's label."

In the original and revised Guidance for Industry there was no mention concerning the use of bolded type font when revising the labels to include the "Rx (or ℞) only" statement. In Section IV of the Guidance entitled "Frequently Asked Questions" Question 3 concerned the prominence and location of the statement. In the reply it was stated "The statement should be prominent and conspicuous, as is required by Section 502(c) of the Act and 321 CFR 201.15."

Based on this prior Guidance, Merck implemented the change to "Rx only" utilizing a bolded font type to meet the spirit of "prominence and conspicuousness" as required by Section 502(c) of the Act and 21 CFR 201.15 rather than increase the font size or change its color for a similar effect. Consequently, we have initiated distribution of labeling using a bolded font type for this change. Converting labeling back to a regular type font would incur significant expense. It is not clear why this change has been made in the Guidance and why bolded font type is no longer suitable. Other methods to ensure prominence and conspicuousness such as increasing font size would be counterproductive to the intent of saving space on the label and changing its color would serve the same purpose as bolding, and, in some cases, may be the more expensive option.

Therefore, for companies who have made good faith efforts to comply with the original Guidance by making the revision to "Rx only", changing this parameter would impose an unnecessary financial burden and would have the unintended effect of causing a substantial environmental impact due to discard of already-completed components.

Recommendation:

Based on the original Guidance, and in keeping with the intent of the proposed regulation, the use of bolded font type for the statement "Rx only" on prescription product labeling should continue to be allowed as outlined in the original Guidance document, since any other measure to ensure prominence and conspicuousness, as required by the updated Guidance, would be less efficient use of space, and, as noted above, use of colored type would have the same effect as bolded type font but may be the more expensive option. This will allow the statement to be prominently displayed on the label without interfering with any other text.

Conclusion:

In conclusion, while Merck supports this change in label text and has taken the necessary steps to ensure that this revision was quickly implemented in packaging across the entire product line, Merck prefers to maintain the prominent bolded type font recently implemented in all Company labeling to allow this revision to be more readily visible to the health care professional and consumer.

We welcome the opportunity to provide comments on this proposal. Questions concerning these comments should be directed to Bonnie Goldmann, M.D. (610-397-2383).

Sincerely yours,

Marie Aldray for B. J. Goldmann

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